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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/003,047	01/05/1998	ALBERT J J VAN OYEN	261922003302	8520

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MORRISON & FOERSTER LLP
3811 VALLEY CENTRE DRIVE
SUITE 500
SAN DIEGO, CA 92130-2332

EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 07/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/003,047	VAN OUYEN ET AL.	
	Examiner	Art Unit	
	David H Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,27,28,42,48,51,54-58 and 61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,27,28,42,48,51,54-58 and 61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 May 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/8/2004</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 8 April 2004 has been entered.
2. Those rejections or objections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments to the claims.
3. The rejection of claims 54-58 under 35 U.S.C. 103(a) as being unpatentable over Cornelissen et al. (U.S. Patent 6,066,491, effective filing date 1/29/91) or Cornelissen et al. (EP 440,304; 8/7/91), either in view of Baird et al. (J. Bacteriol. 172: 1576-1586, 1990) is withdrawn in view of Applicant arguments (pages 11-13 of the Remarks).
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

5. Acknowledgment is made of Applicant's claim for priority under 35 U.S.C. § 119(a)-(d) based upon an application filed in the European Patent Office on 13 September 1990. A claim for priority under 35 U.S.C. § 119(a)-(d) cannot be based on said application, since the United States application was filed more than twelve months thereafter. The Declaration of record indicates that parent Application 07/849,422, filed

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12 June 1992 had been filed as PCT International Application No. PCT/NL91/00171 on 13 September 1991, but U.S. Patent 5,705,375, which issued from a file wrapper continuation of application 07/849,422 makes no assertion of priority to such a PCT application. Applicant has asserted in the response filed 8 April 2004 that application 07/849,422 was filed under 35 U.S.C. § 371 on June 12, 1992 (page 12, 2nd paragraph of the response). The Examiner has reviewed the file wrapper for application 08/253,575, the FWC of application 07/849,422, and found the Form PCT-903, mailed 3 August 1992. Applicant must amend the first line of the specification to read -- This application is a continuation of U.S. Application No. 08/253,575, filed 3 June 1994, now U.S. Patent 5,705,375, which is a file wrapper continuation of U.S. Application No. 07/849,422, filed 12 June 1992, now abandoned, which is the National Stage of International Application No. PCT/NL91/00171, filed in English on 13 September 1991. -
-. Applicant should be advised that PCT/NL91/00171 must have been filed in English to claim the priority date. Until such time as Applicant has clarified the record, the instant application is given the priority date of 12 June 1992 (that of Application 07/849,422) for the purposes of applying the prior art **Specification**

6. The specification is objected to because an incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper; see page 16, lines 19 and 20 of the specification. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory

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material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973). If the material is not considered by Applicant to be essential material, a statement on the record would obviate this objection (See MPEP 608.01(p)(I)).

Information Disclosure Statement

7. The Information Disclosure filed 8 April 2004 has been considered and a signed copy is attached hereto.

Claim Rejections - 35 USC § 112

8. Claims 1, 27, 28, 42, 48, 51 and 54-58 remain rejected and claim 61 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the last Office action mailed 14 October 2003. Applicant's arguments filed 8 April 2004 have been fully considered by they are not found to be persuasive.

Applicants argues that the IDS filed 8 April 2004 includes not only endo-glucanase sequences isolated from a variety of bacterial but also such sequences isolated from a variety of fungi and from the cellular slime mold *Dictyostelium* (page 6, 3rd paragraph of the Remarks). This argument is not found to be persuasive because

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the method of claims 1, 27, 28, 42, 48, 51 and 61 requires that expression of said glucanase results in increased saccharide composition of the transformed plant. As the guidance of the specification is only to other endo-glucanases known in the art at the time of the invention, it is unclear from the specification that those endo-glucanases meeting such a functional limitation have been adequately described as broadly claimed. The specification only describes two endo-glucanases on page 6, lines 31-32. The genus of endo-glucanases is much broader than the 1,3- β glucanase or 1,4- β glucanase described in the specification. Hence, the specification lacks adequate written description for the recombinant DNA expression cassette and vector of claims 54 and 55, and the transgenic plant and bacterial strain of claims 56-58 as broadly claimed.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. At 1406, the court states that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

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See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

9. Claims 1, 27, 28, 42, 48, 51 and 54-58 remain rejected and claim 61 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated from the reasons of record as set forth in the last Office action mailed 14 October 2003. Applicant's arguments filed 8 April 2004 have been fully considered by they are not found to be persuasive.

Applicant argues that exemplary endo-glucanases are presented in the specification, that nucleic acid sequences encoding microbial endo-glucanases were known in the art at the time of filing, and that the activity of endo-glucanases and techniques to assess endo-glucanase activity are well known in the art (page 8, 3rd paragraph of the Remarks). This argument is not found to be persuasive because the art teaches that substrate specificity of glucanases can be of critical importance in

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teaching how to use such enzymes, and that standard methods of determining enzymatic activity of glucanases at the time of Applicant's invention often do not address the issue of substrate specificity (see Esen 1993, in β -Glucosidases Biochemistry and Molecular Biology, Esen editor, American Chemical Society, Washington, D.C., pages 1-3). Hence, simply teaching one of skill in the art how to isolate nucleic acids encoding microbial endo-glucanases does not teach how to use such nucleic acids to increase the saccharide composition in a transgenic plant as broadly claimed.

Applicants argue that the stated object [of the claims] is to modify polysaccharide/saccharide composition such that there is an increase in the saccharide composition of the plant or plant organs, that the nature of the modification, e.g. an increase in the presence of oligo- and/or mono-saccharides, is described as well as its monitoring using conventional assays and that such alteration to a plant phenotype is not highly unpredictable and would not create undue experimentation to obtain or detect. This argument is not found to be persuasive for the reasons given supra.

Applicants argue that Harpster describes over expression of a pepper endo-glucanase [endo-1,4- β -D-glucanase] in a transgenic tomato and observes a 24-37% reduction in non-xyloglucan glycans, a loss of other higher molecular weight matrix glycans but no obvious differences in plant morphology, thus, Harpster demonstrates that expression of a polysaccharide-degrading enzyme (endo-glucanase) in a transgenic plant does indeed result in a modification of the polysaccharide/saccharide

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composition of the plant (page 9, 3rd paragraph of the Remarks). The Examiner concedes this argument.

Applicants argue that Carvalho observes a transgene "gene silencing" phenomenon in only one of five transgenic plant lines, and only in plants homozygous for the transgene derived from that one particular line and that the great majority of the transgenic plant lines reported in Carvalho express the transgene apparently as expected and do not provide evidence for the alleged unpredictability of the claimed invention or for any doubt of the teachings of the specification (page 9, 4th paragraph of the Remarks). This argument is not found to be persuasive because Carvalho teaches that expression of the transgene in the transgenic plant is unpredictable because of gene regulation. Carvalho also teaches that constitutive overexpression of the endo-glucanase did not cause any apparent phenotypic abnormality (page 2295, right column, 4th paragraph). The Examiner notes that Applicant has only provided specific guidance on how to make and use a transgenic plant comprising a microbial α -glucanase, that being α -amylase on page 27 of the specification. The exemplified α -amylase is an endo-glucanase that randomly hydrolyzes the non-terminal α -1,4-glycosidic linkages in both linear and branched substrates and falls within the scope of the instant claims (see Manners 1974, in Annual Proceedings of the Phytochemical Society, No. 10, Plant Carbohydrate Biochemistry, Pridham ed., Academic Press, London England, pages 109-125, see especially pages 113-116). Applicant does not teach how to predictable make and use transgenic plants comprising any microbial

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endo-glucanase wherein the saccharide composition of said plants is increased as broadly claimed without undue trial and error experimentation.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 27, 28, 51, 54-58 and 61 are rejected under 35 U.S.C. § 102(b) as being anticipated by Borriss *et al* (WO 90/09436, published 23 August 1990) taken with the evidence of Hofemeister *et al* (1986, Gene Vol. 49, pages 117-187).

Borriss *et al* disclose a genetic construct encoding a microbial (1,3-1,4)- β -glucanase comprising a CaMV promoter regulatory sequence (pages 15 and 16). Borriss *et al* disclose that regulatable [sic] plant promoters can also be used in said genetic construct (page 16, lines 5-6). Borriss *et al* disclose a maize (corn) plant comprising said genetic construct (claim 60). Borriss *et al* disclose a method of making such a corn plant comprising said genetic construct (paragraph spanning pages 16-17). Borriss *et al* disclose that the genetic construct can comprise a nucleotide sequence encoding a signal peptide, such would direct said glucanase to a cellular compartment (page 15, lines 13-14). Borriss *et al* disclose that the introduction of the genetic information into said plant can be by use of a bacterial vector, hence inherently disclosing a bacterial strain comprising the vector (page 16, line 34). Hofemeister *et al* disclose that the nucleotide sequence encoding the microbial (1,3-1,4)- β -glucanase

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from *Bacillus amyloliquefaciens* used by Borriss *et al* encodes an endo- β -1,3-1,4-glucanase (see Summary on page 177). Hence, Borriss *et al* have previously disclosed all of the claim limitations.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1, 27, 28, 42, 48, 51, 54-58 and 61 are rejected under the judicially created doctrine of double patenting over claims 1-17 of U. S. Patent No. 5,705,375, published 6 January 1998, since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the method of modifying the carbohydrate composition of a plant comprising a transgenic plant comprising a recombinant DNA expression construct encoding a microbial alpha-amylase of claim 1 of the '375 patent renders obvious the claimed method comprising a transgenic plant comprising a

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recombinant expression construct containing a nucleotide sequence encoding a microbial endo-glucanase because the claimed genus in the instant claims encompasses the subgenus/species of the claims of the issued patent. As outlined above the exemplified α -amylase of the issued claims is an endo-glucanase that randomly hydrolyzes the non-terminal α -1,4-glycosidic linkages in both linear and branched substrates and falls within the scope of the instant claims (see Manners 1974, in Annual Proceedings of the Phytochemical Society, No. 10, Plant Carbohydrate Biochemistry, Pridham ed., Academic Press, London England, pages 109-125, see especially pages 113-116).

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application, which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

14. Claims 1, 27, 28, 42, 48, 51, 54-58 and 61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7, 10 and 11 of U.S. Patent No. 5,543,576, published 6 August 1996. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of effecting the conversion of substrates to products in a mixture containing seeds of a transgenic plant modified to contain an expression system for the production of an enzyme heterologous to the seed, wherein said enzyme is a cellulase (endo-1,4- β -D-glucanase) or a glucose isomerase renders obvious the method of modifying the polysaccharide/saccharide composition of a plant of the instant claims, as

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well as the claimed recombinant DNA expression cassette used to make the plant of the instant claimed method and the transgenic plant used in the instant claimed method.

The '576 patent teaches using the α -amylase gene of *Bacillus licheniformis* in an expression cassette to transform a plant (column 20), which is the same α -amylase gene taught in the instant application (page 26 of the specification).

Conclusion


15. Claims 42 and 48 are free of the prior art.

16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.


AH 1638

David H. Kruse, Ph.D.
16 July 2004

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18. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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